## PATENT COOPERATION TREATY

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# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILIT (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

| Applicant's or agent's file reference 2960/121WO   | FOR FURTHER ACTION   | See item 4 below   |  |  |
|--|--|--|--|--|
| International application No.<br>PCT/US2005/044008   | International filing date ( <i>day/month/year</i> )<br>02 December 2005 (02.12.2005) | Priority date ( <i>day/month/year</i> )<br>02 December 2004 (02.12.2004) |  |  |
| International Patent Classification (8th edition unless older edition indicated)<br>See relevant information in Form PCT/ISA/237 |  |  |  |  |
| Applicant<br>CONFORMIS, INC.   |  |  |  |  |

| 1. | This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).                       |  |  |  |  |  |  |
|----|---|--|--|--|--|--|--|
| 2. | This REPORT consists of a total of 7 sheets, including this cover sheet.  |  |  |  |  |  |  |
|    | In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead. |  |  |  |  |  |  |
| 3. | 3. This report contains indications relating to the following items:  |  |  |  |  |  |  |
| ÷. | Box No. I   | Basis of the report  |  |  |  |  |  |
|    | <b>Вох No. II</b>   | Priority   |  |  |  |  |  |
|    | Box No. III   | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |  |  |  |  |  |
|    | Box No. IV  | Lack of unity of invention   |  |  |  |  |  |
|    | Box No. V   | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement  |  |  |  |  |  |
|    | Box No. VI  | Certain documents cited  |  |  |  |  |  |
|    | Box No. VII   | Certain defects in the international application   |  |  |  |  |  |
|    | Box No. VIII  | Certain observations on the international application  |  |  |  |  |  |
| 4. | The International Bureau will co not, except where the applicant n date (Rule 44 <i>bis</i> .2).  | mmunicate this report to designated Offices in accordance with Rules 44 <i>bis</i> .3(c) and 93 <i>bis</i> .1 but nakes an express request under Article 23(2), before the expiration of 30 months from the priority |  |  |  |  |  |

|   | Date of issuance of this report<br>05 June 2007 (05.06.2007) |
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| The International Bureau of WIPO<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland | Authorized officer<br>Beate Giffo-Schmitt                    |
| Facsimile No. +41 22 338 82 70  | e-mail: pt03.pct@wipo.int                                    |

Form PCT/IB/373 (January 2004)

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| PCT  |  | To:   |                                |  |
| NOTIFICATION CONCERNING<br>TRANSMITTAL OF COPY OF INTERNATIONAL<br>PRELIMINARY REPORT ON PATENTABILITY<br>(CHAPTER I OF THE PATENT COOPERATION<br>TREATY)<br>(PCT Rule 44bis.1(c))<br>Date of mailing (day/month/year) |  | SUNSTEIN, Bruce, D.<br>Bromberg & Sunstein LLP<br>125 Summer Street<br>Boston, MA 02110-1618<br>ETATS-UNIS D'AMERIQUE<br>DOCKETED |                                |  |
| 14 June 2007 (14.06.2007)  |  |   |                                |  |
| Applicant's or agent's file reference<br>2960/121WO  |  |   |                                |  |
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|          | see form F   | PCT/ISA/220  | 86   |   | NAL SEARCHING AUTHORITY   |
|          |  |  | -  | (F  | PCT Rule 43 <i>bis</i> .1)  |
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|          | icant's or agent's file<br>form PCT/ISA/22   |  |  | FOR FURTHER A<br>See paragraph 2 belo   |   |
|          | national application N<br>T/US2005/044008  |  | International filing date  | (day/month/year)  | Priority date (day/monthlyear)<br>02.12.2004  |
|          |  |  | both national classificatio  | n and IPC   |   |
|          | /. A61B17/17 A61   |  | John Hatorial Gassillealiu   |   |   |
| •••      | licant   |  |  |   |   |
| o        | NFORMIS, INC.  |  |  |   |   |
|          |  |  |  |   |   |
|          | This opinion co  | ntains indicati  | ions relating to the fo  | llowing items:  |   |
|          |  |  |  |   |   |
|          | Box No. 1 Basis of the opinion   |  |  |   |   |
|          |  |  | pinion   |   |   |
|          | ⊠ Box No. I<br>⊠ Box No. II<br>⊠ Box No. III   | Priority   |  | gard to novelty, inventi  | ve step and industrial applicability  |
|          | 🖾 Box No. II   | Priority<br>Non-establish  | ment of opinion with re  | gard to novelty, inventi  | ve step and industrial applicability  |
|          | ⊠ Box No. II<br>⊠ Box No. III  | Priority<br>Non-establish<br>Lack of unity of<br>Reasoned sta  | ment of opinion with re<br>of invention<br>Itement under Rule 43 <i>1</i>  | <i>cis</i> .1(a)(i) with regard to  | novelty, inventive step or industrial   |
|          | ⊠ Box No. II<br>⊠ Box No. III<br>□ Box No. IV  | Priority<br>Non-establish<br>Lack of unity of<br>Reasoned sta  | ment of opinion with re<br>of invention<br>Itement under Rule 43 <i>t</i><br>citations and explanatio  |   | novelty, inventive step or industrial   |
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International application No. PCT/US2005/044008

#### Box No. I Basis of the opinion

- 1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
- 2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - □ a sequence listing
    - □ table(s) related to the sequence listing
  - b. format of material:
    - in written format
    - in computer readable form
  - c. time of filing/furnishing:
    - $\Box$  contained in the international application as filed.
    - filed together with the international application in computer readable form.
    - furnished subsequently to this Authority for the purposes of search.
- 3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto. has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
- 4. Additional comments:

#### Box No. II Priority

- 1. It is the validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
- 2. This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
- 3. Additional observations, if necessary:

| Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |  |  |  |  |  |  |
|---|--|--|--|--|--|--|
| The questions whether the claimed invention appears to be novel, obvious), or to be industrially applicable have not been examined                      | to involve an inventive step (to be non in respect of:   |  |  |  |  |  |
| the entire international application,   |  |  |  |  |  |  |
| ⊠ claims Nos. 9-13  |  |  |  |  |  |  |
| because:  |  |  |  |  |  |  |
| the said international application, or the said claims Nos. r<br>does not require an international preliminary examination (sp                          | elate to the following subject matter which ecify):  |  |  |  |  |  |
| the description, claims or drawings (indicate particular element<br>unclear that no meaningful opinion could be formed (specify):                       | the description, claims or drawings <i>(indicate particular elements below)</i> or said claims Nos. are so unclear that no meaningful opinion could be formed <i>(specify)</i> : |  |  |  |  |  |
| the claims, or said claims Nos. are so inadequately supported could be formed.  |  |  |  |  |  |  |
| no international search report has been established for the whole application or for said claims Nos. 9-13  |  |  |  |  |  |  |
| the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that: |  |  |  |  |  |  |
| the written form 🛛 has not been furnished   |  |  |  |  |  |  |
| $\Box$ does not comply with th  | e standard   |  |  |  |  |  |
| the computer readable form $\Box$ has not been furnished  |  |  |  |  |  |  |
| does not comply with the  | ne standard  |  |  |  |  |  |
| the tables related to the nucleotide and/or amino acid sequer<br>not comply with the technical requirements provided for in Ar                          | nce listing, if in computer readable form only, do nnex C- <i>bis</i> of the Administrative Instructions.  |  |  |  |  |  |
|   |  |  |  |  |  |  |

□ See separate sheet for further details

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

|    | Box No. V Reasoned statement under Rule 43 <i>bis.</i> 1(a)(i) with regard to novelty, inve<br>industrial applicability; citations and explanations supporting such statement |  |  |  |
|----|---|--|--|--|
| 1. | Statement   |  |  |  |

| Novelty (N)                   |             | Claims<br>Claims | 1-8 |
|-------------------------------|-------------|------------------|-----|
| Inventive step (IS)           |             | Claims<br>Claims | 1-8 |
| Industrial applicability (IA) | Yes:<br>No: | Claims<br>Claims | 1-8 |

2. Citations and explanations

see separate sheet

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#### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

International application No.

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#### Re Item III.

In accordance with Rule 67.1(iv) PCT, claims 9-13 are exempted from international preliminary examination, since they describe methods of medical treatment. In particular, the method described in independent claim 9 includes the step of drilling an aperture into the surface of the patella, which is part of a method of treatment of a human or animal body by surgery and is therefore exempted from examination (see the PCT International Search and Preliminary Examination Guidelines, Ch. 9.08).

#### Re Item V.

..**t** :

- Reference is made to the following documents:
   D1: US 5 129 908 A (PETERSEN ET AL) 14 July 1992 (1992-07-14)
   D2: US 5 895 908 A (UEDDINCTON ET AL) 99 March 1999 (1992-07-14)
  - D2: US 5 885 298 A (HERRINGTON ET AL) 23 March 1999 (1999-03-23)
- 2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Document D1 discloses (the references in parentheses applying to this document) a drill-guide for engaging a surface of a patella, the drill guide comprising a mould (70, 80) having a first surface (128) that is configured to substantially match the surface of the patella (see column 6, line 38 to column 8, line 35, column 4, lines 50-64 and figures 1, 3 and 4).

Thus, document D1 discloses all of the technical features of claim 1. in addition, the aforementioned disclosure of document D1 anticipates the subject-matter of dependent claims 2-8.

The same result with respect to the lack of novelty of the subject-matter of claims 1-3 and 6 is obtained with document D2 (see column 4, lines 28-40, column 9, line 33 to column 10, line 9 and figure 3).

Therefore, the subject-matter of claims 1-8 is not novel (Art. 33(2) PCT) and as such these claims do not meet the criteria of Article 33(1) PCT.

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

International application No.

- 3. Claim 1 has not been delimited with respect to the closest prior art (document D1 or D2), which would have been appropriate (Rule 6.3(b) PCT).
- 4. Reference signs have not been used throughout the claims, which would have been appropriate (Rule 6.2(b) PCT).
- 5. The documents D1 and D2 should have been identified in the description and the background art disclosed therein briefly discussed (Rule 5.1(a)(ii) PCT).

Form PCT/ISA/237 (Separate Sheet) (Sheet 2) (EPO-January 2004)